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VIA ECF – [redacted]

The Honorable Douglas E. Arpert
United States District Court
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *Par Pharm., Inc. et al. v. Sandoz Inc.*, No. 3:18-cv-14895-BRM-DEA

Dear Judge Arpert:

We represent Plaintiffs ("Par") in the above-captioned Hatch-Waxman Act ANDA litigation against Sandoz, in which Par asserts that Sandoz's proposed generic version of its Vasostrict® products infringe five of its patents listed in the "Orange Book" for Vasostrict®. Earlier today, Your Honor entered an Order moving up by a week—to Tuesday, January 21—the date for the next case management conference in this case, in order to have it coincide with the *Markman* hearing to be held that same day.

We write to apprise the Court of two issues we intend to raise at that conference:

1. That the Court overrule Sandoz's improper objection to producing documents created after the date it served its "Paragraph IV" notice[1] on Par and compel Sandoz to produce relevant documents responsive to Par's requests, even if created after that date; and

[1] A "Paragraph IV" notice is a notice by a generic manufacturer to the manufacturer of a branded product at issue that it has filed an ANDA seeking FDA approval to make and sell a generic version of the branded product prior to expiration of patents covering that product that are listed in the FDA's "Orange Book." It is the service of such a Paragraph IV notice that triggers the commencement of ANDA patent litigation, as in this case.

2. That the Court extend the deadline for completing fact discovery in view of the need for such documents and Sandoz's impending FDA submission, which will contain highly relevant documents and information not presently available.

Sandoz's Improper Date Cutoff:

Amongst its objections to Par's document requests, Sandoz has objected to producing documents (other than FDA communications) if they were created after August 31, 2018, which is the date of Sandoz's Paragraph IV notice to Par. *See* Ex. A (excerpt of RFP response) at General Objection 11. Since that time, Par has assiduously insisted that Sandoz produce relevant, responsive documents without regard to that date, which itself has no bearing on the relevance or discoverability of Sandoz's documents. Par had understood that Sandoz had agreed not to withhold documents based on that objection, but recently discovered that Sandoz is, in fact, refusing to search for and produce highly relevant documents based on their date of creation. That is improper.

Of particular concern are documents identifying, characterizing and quantifying the impurities in Sandoz's proposed generic products. That's because many of the asserted claims in this case include limitations reciting the identity and amount of particular impurities. *See, e.g.*, Ex. B (claims of the '785 patent, with "SEQ. ID Nos." referring to impurities listed in Table 1 of the specification). In a transparent attempt to avoid creating evidence that could be used against it if Par sued it for infringing its patents, [redacted] *See* Ex. D, at ¶¶ 5 and 9.[2] [redacted]

[2] Sandoz submitted ANDAs for two separate products, a "single-dose vial" product and a "multiple-dose vial" product. The FDA letters attached hereto relate to Sandoz's multiple-dose vial product, [redacted]

[redacted]. *See* Ex. E, at ¶¶ 4, 13-15, 21 and p. 8. [redacted]

Sandoz undoubtedly has been working hard [redacted]. Sandoz did not produce [redacted] until September 2019, months after they were received by Sandoz [redacted] When Par raised with Sandoz the noticeable absence of documents [redacted] from Sandoz's production, Sandoz advised that it hadn't searched for or produced them because its arbitrary and improper date cutoff—[redacted]. After further conferring with Par, Sandoz agreed to make a limited production but refused to withdraw its improper date restriction.

As described, the documents Par seeks are highly relevant to disputed issues in this case. Indeed, one of Sandoz's principal non-infringement contentions is its assertion that Par has not demonstrated [redacted]. *See* Ex. F (excerpt of Non-Infringement Contentions), at 27-28. Sandoz cannot be permitted to escape infringement [redacted] because they were created after the ANDAs were submitted.

Accordingly, the Court should overrule Sandoz's improper objection and compel Sandoz to search for and produce relevant, responsive documents without regard to the date on which they were created.

Extension of the Fact Discovery Cutoff:

The current deadline for completing fact discovery is January 31, 2020. Both sides agree that additional time is needed, and have agreed to jointly request an extension until at

least March 2, 2020.[3] However, Par requests a further extension in view of the deficiencies in Sandoz's production identified above, as well as to allow time for the production and discovery relating to [redacted]

[redacted].[4] Thus, it is necessary to extend the fact discovery cutoff in order to allow Par to obtain copies of and take discovery regarding those critical documents. Any fact depositions taken now will necessarily be incomplete and have to be re-opened once these documents are produced, and any expert reports would likewise necessarily be incomplete and need supplementation. It would highly unfair, inefficient, and prejudicial to require Par to proceed based on only partial information and discovery.

Accordingly, the Court should extend the fact discovery cutoff until at least May 17 [redacted], and schedule a case management conference for a week or two in advance of that date, to revisit the issue and assess whether any further extension is required and the further schedule for other applicable deadlines.

Sandoz cannot claim that it would be unduly prejudiced by the requested extension, as any prejudice is of its own making. [redacted]. *See* Ex. G (compilation

[3] Indeed, Sandoz recently requested and obtained, without objection from Par, an extension of the deadline to amend pleadings to January 22, 2020. Dkt. 76.

[4] Because this is an ANDA case, Sandoz does not yet have a product on the market, but is instead seeking FDA approval to make and sell its proposed products, and the relevant infringement inquiry involves an assessment of the properties of the product that Sandoz is likely to sell if and when it obtains FDA approval. Thus, the belated production of this delayed information is particularly important in cases of the present type.

of exemplary emails discussing [redacted] combined with its improper date objections, has prevented Par from completing necessary fact discovery within the established schedule. Sandoz should bear the impact of its calculated decisions, not Par.

Respectfully submitted,

/s/ *Brian M. Goldberg*

Brian M. Goldberg

cc: All Counsel of Record (via ECF and e-mail)